K120784

JUN - 8 2012

PULPDENT CORPORATION

80 Oakland Street
Watertown, MA 02472
USA

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510(k) SUMMARY

March 13, 2012

Kenneth J. Berk
80 Oakland Street
Watertown, MA 02472 USA

Telephone: 617-926-6666
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DEVICE:
Trade Name: *Pulpdent Tuff-Temp 2.0*
Classification Name: Temporary Crown and Bridge Resin
Class: II **FDA Product Code:** 76 EBG, 21 CFR Part 872.3770

PREDICATE DEVICES:
Pulpdent Tuff-Temp
Luxatemp, DMG

DESCRIPTION AND INTENDED USE:
Pulpdent Tuff-Temp 2.0 is a dual-cure, glass-filled, resin composite used by the dental professional to make a temporary prosthesis, such as a crown or bridge, to be used until a permanent restoration can be fabricated.

COMPARISON WITH PREDICATE PRODUCTS:
Pulpdent Tuff-Temp 2.0 is substantially equivalent in design, composition, performance and intended use to the predicate products. The predicate products have been found substantially equivalent under the 510(k) Premarket Notification process as Class II Dental Devices under CFR 872.3770. *Tuff-Temp 2.0* is an enhanced version of the original *Tuff-Temp* with improved esthetics, reduced oxygen inhibited layer and lower heat rise on setting.

Product	Description	Intended Use	Composition
Pulpdent Tuff-Temp 2.0	Dual-cure, glass-filled composite material in two parts	To make a temporary prosthesis, such as a crown or bridge, for use until a permanent restoration can be fabricated.	Blended dimethacrylate resins Chemical and Photo-initiators Barium glass and submicron silica fillers
Pulpdent Tuff-Temp K081810	Dual-cure, glass-filled composite material in two parts	To make a temporary prosthesis, such as a crown or bridge, for use until a permanent restoration can be fabricated.	Blended dimethacrylate resins Chemical and Photo-initiators Barium glass and submicron silica fillers
DMG Luxatemp Solar K013674	Dual cure, bis-acryl composite material in two parts	To make a temporary prosthesis, such as a crown or bridge, for use until a permanent restoration can be fabricated.	Bis-acryl resins (Urethane dimethacrylate, aromatic dimethacyrlate, glycol methacrylate) Chemical and Photo-initiators Barium glass and submicron silica fillers

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SUMMARY OF PERFORMANCE TESTING – BENCH:

The following test results demonstrate that *Tuff-Temp 2.0* performs as intended:

Flexural strength	84.0 ± 4.0 MPa
Compressive strength	205.0 ± 18.0 MPa
Deflection at break	2.3 ± 0.3 mm
Heat rise	5.4°C

	Self-cure	Light cure
Initial setting time	90 seconds	20 seconds
Final self-cure setting time	5 minutes from beginning of mix	Not applicable

BIOCOMPATIBILITY:

Pre-production clinical evaluations of Tuff-Temp 2.0 by dentists in the field and by dentist consultants were positive. Tuff-Temp 2.0 has been sold in Europe as a CE marked medical device for the past four months. Its use in clinical practice has met both user and patient needs and there have been no reports of adverse events.

The original Tuff-Temp has been on the market for two years. Field Reports from sales people, dentists, and other customers have praised Tuff-Temp for its qualities. During that time there have been no reports of adverse events, i.e., allergic reactions, soft tissue irritation, etc. There is sufficient similarity between Tuff-Temp and Tuff-Temp 2.0 to expect that it will have equivalent biocompatibility.

CONCLUSION:

From the above comparisons, the bench testing and more than ten years of problem-free use of similar temporary crown and bridge resins in the dental profession, it can be concluded that *Pulpdent Tuff-Temp 2.0* is substantially equivalent in design, composition, performance and intended use to the predicate products listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN - 8 2012

Mr. Kenneth J. Berk
Director
Pulpdent Corporation
80 Oakland Street
Watertown, Massachusetts 02472

Re: K120784
Trade/Device Name: Pulpdent Tuff-Temp 2.0
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Code: EBG
Dated: March 13, 2012
Received: March 15, 2012

Dear Mr. Berk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120784

Indications for Use

510(k) Number: K120784

Device Name: ***Pulpdent Tuff-Temp 2.0***

Indications For Use:

Pulpdent Tuff-Temp 2.0 is a dual-cure, glass-filled, resin composite used by the dental professional to make a temporary prosthesis, such as a crown or bridge, to be used until a permanent restoration can be fabricated.

Prescription Use _X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runyon

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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